6021221_PRO4000_S1 Seite 1 Freitag, 17. März 2006 11:19 11

BRAUN

WelchAllyn®

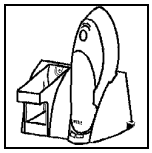
PRO 4000

ThermoScan

Type 6021

Welch Allyn

Service Documentation



Part Number: 701627

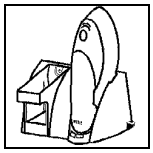
Rev. G

This documentation provides only technical information - technical data, calibration instruction, general information and regulations for medical products.

The function of the thermometer is described in the Operating Instructions, Welch Allyn P/N 701622

Technical data:

Display:	LCD-Display.
Display resolution:	0.1 ℃ / ℉.
Displayed temperature range:	20.0 ℃ - 42.2 ℃ (68 .0 ℉ - 108.0 ℉).
Work place temperature range:	10.0 ℃ - 40.0 ℃ (5 0.0 ℉ - 104.0 ℉).
Work place humidity:	up to 95 %.
In the range between: the accuracy of allowable tolerance with probe cover is:	35.5 ℃ - 42.0 ℃ (95.9 ℉ - 107.6 ℉). ± 0.2 ℃ (± 0.4 ℉).
Outside the range from: the accuracy of allowable tolerance with probe cover is:	35.5 ℃ - 42.0 ℃ (95.9 ℉ - 107.6 ℉). ± 0.3 ℃ (± 0.5 ℉).
Probe tip:	heated up to approximately 37°C.
Power supply:	rechargeable Braun battery-pack with base-station and smart plug or 2 1.5 V type AA (LR 6) batteries.
Smart plug:	100-240 V - input / 12 V – output.
Base-station:	12 V - input / approx. 2.4 V – output.
Battery-life time:	3 month (with *****) / 1000 measurements.
Rechargeable battery lifetime:	3 month / 500 measurements per charge.
Rechargeable battery charging:	Thermometer stored in basis-station.
Rechargeable battery charging time:	14 hours.
Base-station function indications:	1 LED, green for power connection 1 LED, yellow for charging indication.
Electronic anti-theft *****:	for Pro 4000 appliances only and with the base-station in use.
Automatic turn off:	If no button is pressed within 60 seconds, the appliance will turn off automatically.
Manual turn off:	Push I/O mem - button for >3 seconds.



Part Number: 701627

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General hints

Production code Near the battery storage LOT **4042**.
4 = Year / **042** = Day.

Attention: Do not dispose of empty batteries or defective rechargeable batteries in household waste. Disposal can take place at appropriate collection sites provided in your country

Hint: Type BF equipment

This appliance conforms to the following standards: DIN EN 60601-1 <<Medical electrical equipment>>-Part 1: General requirements for safety.

Hint: CE 0297 This product conforms to the provisions of the EC directive 93/42/EEC (Medical Device Directive).

Labour Group: **03**

Special tools:

The accuracy of infrared thermometers can only be tested with a blackbody device (BB-3200 Series, no longer available for purchase) or the 9600 PLUS Calibration Tester.

The Model 9600 PLUS Calibration Tester can be ordered through Welch Allyn Customer Service (see page 8) for Welch Allyn contact information.

Model	Welch Allyn P/N	Braun P/N
9600 PLUS Calibration Tester	01802-110	N/A

The following additional data will be necessary:

Bill to address

Ship to address

Quantity

Billing contact person with fon/fax extension

Shipping contact person with fon/fax extension

Shipping method

Purchase Order / Credit Card

The blackbody has to be calibrated every 12 months by the manufacturer. Contact Welch Allyn Customer Service to get a Return Material Authorization number to have your unit calibrated. Refer to Customer Service Listing (see page 8) for Welch Allyn contact information.

Please direct all requirements and questions concerning blackbodies directly to the Welch Allyn Service Center. Refer to Customer Service Listing (see page 8) for Welch Allyn contact information.

General:

Braun ThermoScan infrared thermometers are classified as medical devices. This implies that the manufacturer, the distributor and all service functions have to fulfil certain legal requirements.

Special care has to be taken, to ensure that only products are handed back to the consumer, which are safe and perform according to its specifications. Furthermore, you are obliged to notify Braun Corporate Quality of any unusual defects of the appliance (see also section "customer complaints").

Products sent in by consumers as defective, must be checked thoroughly for any technical deficiencies. If there is any doubt about the performance of the unit, it must be exchanged. A repair, except cleaning, is not possible and strictly forbidden.

If the result of the check shows, that the product is working within specifications, it will be sent back to the consumer. In this case it is important to include information on the condition of the unit that was initially received as defective and to give guidance for the correct use of the appliance.

Initial inspection:

The checking should always start with a visual inspection of the unit for any external damage. Especially the probe tip and probe cover should be examined for any dirt (earwax), which could adversely affect the measuring accuracy.

After pressing the “On” button, the unit performs a self-test and all segments of the unit should show up. For any error messages refer to technical data and troubleshooting sections or to use instructions.

The measuring accuracy can only be tested with a blackbody (BB-3200) or 9600 PLUS, which has a precisely defined temperature.

Calibration general:

Checking the measuring accuracy with blackbody BB 3200 or 9600 PLUS

NOTE: It is recommended that the PRO-4000 have an Operational Verification performed annually using the 9600 Plus Blackbody device.

- Testing must only be done in **Calibration mode** (see page 6).
- Use **a new** probe cover for calibration check (transparent protection cap).
- Make sure that...

  The ambient temperature is within the range 20...25 ℃ and is stable (no drafts).

  The appliances to be checked have had time to adapt to ambient temperature, i.e. they have been placed unpacked in the room for at least half an hour prior to the test.

  After reaching the calibration mode (CAL) wait for 1 minute, insert the appliance into the black body and wait for 3 seconds again to start the measuring.

  Wait about 1 minute before taking repeat measurements; during waiting, the unit should be put down and not kept in hand.

  A series of 3 measurements should be taken. All three measurements should be with in the specific range.

- Due to the design of this black body, its emission factor is only 0.99. Since PRO/IRT 4000 models are calibrated on a blackbody with emission factor 1.00 in the factory, a correction has to be made for the black body effective temperature. This correction is -0,1℃ for PRO/IRT 4000. Due to the heated probe tip, this value is different compared to PRO/IRT 3000.
- Appliances with readings outside the permissible range where the probe tip is contaminated can be cleaned carefully with a cloth soaked with alcohol. After cleaning wait at least 5 minutes before retest.
- All measured values must be documented according to Welch Allyn Quality procedures, stating the date of measurement, the serial number of the unit, the measured values and the final decision. All data will be documented via SAP or current data collection system.

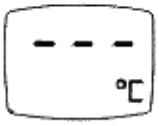
Calibration Mode:

To enter the calibration mode, perform the following steps:

- Use **a new** probe cover for calibration check.

- Turn the product on by push the I/O mem -button. Following symbols and functions will be shown on the display.

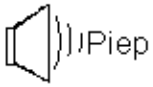
- Automatic self-check.



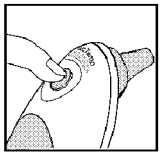
- After few seconds a beep signal is audible, the display shows these symbols.

- Push the I/O mem -button again and **keep it pressed** for the following steps:

- After approximately 3 seconds the "**OFF**"-symbol is flashing on the display.



- After approximately 5 more seconds a beep signal is audible, now ...
  release the I/O mem -button **immediately**.



The product is now in calibration check mode: the display is flashing and showing "**CAL**" and " **- - -** " alternately. The probe tip is heated up to the correct temperature.

After each measurement the display is flashing and showing "**CAL**" and only (two) " **- -** " alternately, the probe tip is not heated up. No measurement is possible.

Push the "**start**" - button for new heating up of the probe tip. The appliance will show again ("**CAL**" and "**- - -**"). It is now ready for a new measurement.

Calibration:

Follow the operating instructions for the BB-3200 or 9600 PLUS closely.
The measured value must be within: **39.7 °C** to **40.1 °C**
(**103.5 °F** to **104.3 °F**).

NOTE: The measured temperature will vary with ambient temperature.

Advanced Display
(High resolution))

- Calibration mode must be activated: the display is flashing and showing "**CAL**" and "**- - -**" alternately.

- One temperature measuring **with probe cover** must be done.

- Push once the I/0 mem - button short time.

- High resolution mode: the display is flashing and showing "**hr**" and measured temperature e.g "**736**" (**37.36** = hundredth °C) alternately. The first digit will be not showing.

- Push once again the I/0 mem - button short time.

- Ambient temperature mode: the display is flashing and showing "**AT**" and ambient temperature e.g. "**23.6 °C**" alternately.

- Push once again the I/0 mem - button short time.

- Probe tip temperature mode: the display is flashing and showing "**ST**" and probe tip temperature e.g. "**37.0 °C**" alternately.

- Push once again the I/0 mem - button short time for reset to the first display ("**CAL**" and "**- - -**").

For leaving the CAL-mode wait approx.4 minutes, the appliance will turn off automatically or push I/0 mem -button for > 3 seconds.

Customer complaints:

Welch Allyn encourages all service centers to report customer complaints.

This information is valuable for the improvements of products.

All complaints where it is alleged, that our product has caused or contributed to a death or a serious deterioration in the state of health of a patient, user or other person, must be reported immediately to your local Welch Allyn Organization.

A serious deterioration in the state of health can include a life-threatening illness or a condition necessitating medical intervention to prevent permanent damage.

Also all cases should be reported where the circumstances indicate, that the incident was such that, if it occurred again, it may lead to death or serious deterioration in health.

Yearly Calibration of Professional units:

NOTE: It is recommended the PRO-4000 device have an Operational verification performed annually using the Model 9600 Plus Blackbody device.

In general, the accuracy for the PRO-4000 unit should be checked any time you suspect the unit is not reading correctly.

Some countries, e.g. Germany, require by legislation a regular check of the measuring accuracy for all medical devices used by professionals.

For infrared thermometers, this check must be done yearly and it is required to verify the measuring accuracy for the full temperature range. This implies to test at three different temperatures the correct reading and to document the results in a test protocol.

If similar regulations should apply for your country, please contact your Welch Allyn Service Center for details on necessary equipment and procedures. Please note that the above described test procedure with the BB 3200 is not sufficient for this purpose.

The 9600 PLUS Calibration device should be used to verify these parameters.

The PRO-4000 can't be calibrated in the field. By using the Black Body device, you can verify accuracy of the unit only.

Authorized Welch Allyn The following is a listing of authorized Welch Allyn Service Centers and Customer Service contact numbers**:**

United States Service Center

Welch Allyn
North Dock
4619 Jordan Road
Skaneateles Falls, NY 13153
Customer Service: 800-535-6663

Service Fax: 315-685-3361

Canada Service Center

Welch Allyn Canada
160 Matheson Blvd. E

Unit 2
Mississauga, ON L4Z 1V4

Customer Service: 905-890-0004

Service Fax: 905-890-0008

Australia Service Center

Welch Allyn Australia
The Metro Centre Unit 5

38-46 South Street
Rydalmere, NSW 2116

Customer Service: 61-2-9638-3000

Service Fax: 61-2-9638-3500

EMEA Service Center

Welch Allyn GMBH

Product Service Center
Zollerstrasse 2-4
Jungingen, 72417

Germany

Customer Service: 011 49 7477 9271 0

Fax: 011 49 7477 9271 90

South Africa

Welch Allyn South Africa
394 Surrey Ave.
Ferndale

Randburg, GP 2194

Customer Service: 011-2711-777-7509